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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/955,657

09/18/2001

Richard E. Wooley

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/955,657	Applicant(s) WOOLEY ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 10/9/07.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 2, 5-9, 11-15, 18, 21, 22, and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fischetti et al (USPN 6,423,299 hereafter '299) in view of Raad et al (USPN 6,267,979 hereafter '979). The claims are drawn to a method of inhibiting the proliferation of a bacterial infection in a skin injury by applying a topical formulation comprising a chelating agent and an antibacterial agent.

4. The '299 patent disclose a method of inhibiting the proliferation of bacterial infections in various locations including burns and oral mucosa (abstract, claims, col. 8, lin. 12-35), wherein a composition comprising a chelating agent and an active antibacterial formulation is applied to the injury (claims, examples, col. 9, lin. 62-col. 10, lin. 5). The chelating agent includes ETDA (claims 5) and the antibacterial agents include neomycin erythromycin, minocycline, tetracycline, and others in a concentration from 0.5-10% (col. 9, lin. 19-28). The chelating agents are included in such a way as to synergistically enhance the other components in the formulation (col. 11, lin. 30-32). The formulation comprises phosphate buffers that regulate the

pH of the formulation from 5.5-7.5 (col. 7, lin. 55-60). The bacterial infections that are treated with the formulation include both Gram negative and positive bacterium such as *Pseudomonas* and *Staphylococcus* (col. 3, lin. 43-47, col. 4, lin. 15-20). The formulation includes carriers such as gel-forming polymers and thickening agents (col. 8, lin. 41-col. 9, lin. 12). The reference, though disclosing the synergistic relationship of the chelating agents to the remains in formulation is silent to the specific concentration.

5. The '979 patent discloses a disinfecting composition comprising a synergistic combination of chelating agents and antimicrobial agents (abstract, example 5). The chelators include various EDTA derivatives along with Diethylene triamine pentaacetic acid (DPTA), and triethylene tetramine dihydrochloride (TRIEN) while the antibacterial agents include minocycline, oxytetracycline, tetracycline, gentamicin and erythromycin (example 5). The EDTA is present in concentrations from 0.1 –10,000 ppm (col. 4, lin. 35-40). More specifically in one embodiment of the invention the EDTA is present in a concentration of 30 g/L, which is approximately 102 mM (example 4). It is the position of the Examiner that the concentration of chelators is merely an optimizable limitation as long as synergy is maintained. In each embodiment of the '979 patent synergy is maintained. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

6. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the

invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

7. Regarding the claims limitation reciting the identification of a bacterial infection, determining the MIC and concentrations of the chelators and antibacterial agents, it is the position of the Examiner that such limitation are inherent to any treatment method and would be obvious to any artisan of ordinary skill. These steps are basic treatment steps and would be encompassed in the routine practice of the invention of the '99 and '979 patents. These steps are merely a recitation of inherent procedures practiced by every artisan of ordinary skill in the field of bacterial infections and do not impart patentability to the claims.

8. With these things in mind it would have been obvious to follow the suggestions and teachings of the prior art in order to provide an improved method of treating bacterial infections. The artisan of ordinary skill would have been motivated to combine the chelating concentration of the '979 patent into the treatment method of the '299 in order to maintain the synergistic properties of the components and improve the treatment of the infection. One of ordinary skill in the art upon combining these teachings, suggestions and disclosures would have expected a treatment method suitable for the disinfecting surface injuries.

9. Claims 1, 2, 8-9, 11-15, 18-22, and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fischetti et al (USPN 6,423,299 hereafter '299) and Raad et al (USPN 6,267,979 hereafter '979) in view of Cuny et al (USPN 6,207,679 hereafter '679). The claims are drawn to a method of treating specific injuries.

10. As discussed above the combination of the '299 and '979 patent provides a method of treating bacterial infections in the skin by combining chelating agents, antibacterial agents and carriers in a synergistic combination. Burns are disclosed in the '299 patent as well as infections in the respiratory system, oral and vaginal mucosa. The reference is silent to ulcers, scrapes, bruises, and lesions. These injuries can also be treated in a similar fashion as disclosed in the '679 patent.

11. The '679 patent teaches the use of antimicrobial agents in the treatment of infections (bacterial/fungal) in wounds such as burns, ulcers, scrapes and bruises (abstract, col. 34, lin. 40-55). The formulations can be used to sterilize medical devices or treat bacterial or fungal infections on internal mucosa, both orally and vaginally (*Ibid.*). Formulations include solutions, elixirs and mouthwashes (col. 38, lin. 46-57). The formulation is effective against both Gram-positive and negative bacterial genus such as *Pseudomonas* and *Staphylococcus* (col. 32, lin. 17-39). The formulation comprises various antimicrobial agents such as penicillins, amino glycosides, and cephalosporins along with carriers and chelators such as EDTA (col. 36, lin. 7-16; col. 38, lin. 19-20). A skilled artisan would have been motivated by these teachings to administer the formulation of the '299 and '979 combination to the skin for wound treatment as taught by '679.

12. With these things in mind one of ordinary skill in the art would have been motivated to follow the teachings of '679 to combine biocidal compounds such as those found in both '679 and '299 in order to treat Gram-positive or negative bacterial infections. The '299/'979 combination teaches the importance of a synergistic relationship between the chelator and the biocide, while the '679 teaches the varying methods of application. The minimum inhibitory

concentration (MIC) for each compound would be known by one of ordinary skill in the art as shown in the '679 patent. It would have been obvious to follow the suggestions of '299/979 combination in order to topically treat bacterial infections with an expected result of a method of treating infected wounds.

13. Claims 1, 2, 5-15, 18, 21, 22, 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fischetti et al (USPN 6,423,299 hereafter '299) and Raad et al (USPN 6,267,979 hereafter '979) in view of Kruse et al (USPN 5,646,151 hereafter '151). The claims are drawn to method of treating a bacterial infection with a specific biocide.

14. As discussed above the combination of the '299 and '979 patents provide an improved method of topically treating bacterial infections in various surfaces. The formulation includes various antibacterial and microbial compounds and suggests the inclusion of any compounds that would fight bacterial infections. The combination is silent however specifically to amikacin. This substitution of a specific well known compound into a formulation is obvious. This compound is known to work as an antibacterial agent as seen in the '151 patent.

15. The '151 patent discloses topical formulations comprising chelating agents such as EDTA and antibiotic agents such as neomycin, amikacin and tetracyclines (col.33, lin. 3-38; col. 34, lin. 25-48; col. 41, lin. 59-col. 43, lin. 54). The reference establishes the knowledge in the art of combining chelating agents and antibiotic/fungal agents in order to treat skin injuries topically. A skilled artisan would be motivated to include the antibiotics of the '151 patent in order to treat a wider range of bacterial infections.

16. With these things in mind, one of ordinary skill in the art would have been motivated to combine the compounds of the '151 patent into the combination of '299/'979 in order to treat a wider range of bacterial infections. It would have been obvious to combine the teachings with an expected result of a topical wound healing formulation capable of treating a wider range of infections.

Response to Arguments

17. Applicant's arguments filed 10/09/07 have been fully considered but they are not persuasive. Applicant argues that:

- a. The '979 patent is non analogous art and would not be a source of information regarding bacterial infections.

18. Regarding this argument, applicant is reminded that first the '979 patent is a secondary patent used to establish the level of skill in the art regarding a concentration of chelator agents relative to the antibacterial agents and not a primary anticipatory reference. Second the problems of the '979 patent and that of the instant claims are the same. Clearing a bacterial population with a composition comprising a chelator and antibacterial compound where the compounds exist synergistically in order to enhance each other's effectiveness. The new rejection comprises a patent that also uses a synergistic combination of components in order to clear bacterial populations. For these reasons the '979 patent continues to supplement the rejection.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1,2,5-11 and 56-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 12-15, 18-21, 25-29, 43 and 44 of copending Application No. 10/739,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of treating a wound with a composition comprising chelators and antibacterial agents. The claims recite the same chelators and antibacterial agents. Although the claims of the '841 patent include further components, the claims of the instant claims are open to further components that do not change the material properties of the invention. For these reasons the claims of the instant claims would act as obviating art over the '841 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Micah-Paul Young
Examiner
Art Unit 1618


Mp Young


DAMERON L. JONES
PRIMARY EXAMINER